

Applicants: Lionel Vedrine  
Serial No.: 10/520,981  
Filing Date: August 29, 2005  
Docket No.: P-5753 (102-627 PCT/US)  
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**REMARKS**

Reconsideration of the application is respectfully requested.

Claims 1-8 are in the application.

Through this amendment, the Specification, particularly, the Abstract and one paragraph, have been amended. In addition, claims 6, 7 and 8 have been amended. It is respectfully submitted that all of the amendments are in form only and do not require further searching. As such, it is respectfully submitted that all of these amendments should be properly entered.

In the Official Action, the Examiner indicated that the reference FR 2 750 051 had not been considered because a concise explanation of relevance was allegedly not provided. On March 22, 2005, an Information Disclosure Statement was filed in this case, which originally cited this French reference. In addition, a copy of an International Search Report was provided with the March 22, 2005 Information Disclosure Statement from corresponding PCT Application No. PCT/FR2003/002252. The French reference was indicated in the Search Report to be of the "A" type. As set forth at MPEP §609.04(a)(III), "the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the Search Report or action which indicates the degree of relevance found by the foreign office. This may be an

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explanation of which portion of the reference is particularly relevant, to which claims it applies or merely an 'X', 'Y', or 'A' indication on a Search Report." As such, the submission of the Search Report with the indication that the reference is of the "A" type satisfies the requirement for a concise explanation of relevance. It is respectfully submitted that the reference FR 2 750 051 was properly submitted with all necessary requirements and needs to be properly considered.

The Examiner objected to the drawings under 37 C.F.R. §1.83(a) asserting that a number of features are not shown in the drawings. First, the Examiner asserted that the "means for holding a needle in position", "the means for holding a container in position", and "the respective means for operating" are not shown. Claims 7 and 8 recite specific features which may constitute the claimed means. In addition, the Examiner further asserted in the Office Action that certain components from claims 7 and 8, namely the "needle-supporting part with at least one locking means and at least one tab" and "engagement means integral with the plunger and the at least one tab" are not shown in the drawings. All of these features are discussed in detail at paras. 42-44, 50, and 55-57 of the relevant application as published. In addition, the features are clearly shown in Figs. 6-8.

The Examiner further asserted that the "pierceable zone of the piston" is not shown in the drawings. The piston is element 11 and is shown in the drawings, including the "pierceable

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zone". Finally, the Examiner also asserted that the "distal wall perpendicular to the axis of the needle" is not shown. Reference is made to Fig. 7, where the distal wall is shown located at the end of the housing and about the needle. It is respectfully submitted that all claimed features are in fact shown in the drawings.

In the Official Action, the Examiner objected to the drawings "because many of the reference characters are not clear." The Examiner stated that "[a]ll of the reference characters should be checked to make sure they are clear." The reference characters have been checked, and, it is respectfully submitted that all of the reference characters are clear.

The Examiner objected to the Specification on two bases. First, the Examiner objected to the Abstract for including the terms "said" and "means". The Abstract has been amended herein to avoid the use of such terms. Second, the Examiner objected to the Specification as allegedly failing to provide proper antecedent basis for the noted limitation. In response, the Specification has been amended to include relevant language. It is respectfully submitted that the Specification, as amended, is in accord with standard U.S. practice.

The Examiner objected to claims 7 and 8 for allegedly including insufficient antecedent basis. These claims have been amended to match the language of claim 1 and sufficient

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antecedent basis is provided. It is respectfully submitted that claims 7 and 8 are in accord with standard U.S. practice.

The Examiner rejected claims 6-8 under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner objected to the phrase "to a distance". In response, claim 6 has been amended to state "the needle projects, in the injection position, from said distal wall to a distance". It is respectfully submitted that claim 6, as amended, is in accord with 35 U.S.C. §112.

The Examiner rejected claims 1-8 under 35 U.S.C. §102(e) as being allegedly anticipated by Barker et al. (U.S. Patent No. 6,569,115). In particular, the Examiner relied on the embodiment shown in Figs. 13-18.

Barker et al. is directed to a pre-filled retractable needle injection device. With reference to the embodiment of Figs. 13-18, a vial 170 is provided in which is disposed medicinal fluid. (Col. 9, ll. 58-59). A plug 90 is disposed in the vial 170 "having a plurality of axially-spaced circumferential ribs 192 that form a fluid-tight seal between the plug 190 and the internal surface of the vial 170." (Col. 9, ll. 62-25). The medicinal fluid is accessed by a rear needle 116 which

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pierces the plug 190. (Col. 10, ll. 3-13). At all times, the plug 190 maintains a fluid-tight seal with the vial 170. (See, e.g., col. 10, ll. 24-26, ("Additionally, the circumferential ribs 192 maintain a fluid-tight seal between the plug and vial while the vial slides over the plug.")).

Claim 1 is directed to a device for injecting a product which includes "a container containing the injectable product" and "a piston engaging the container and so shaped that, in a first configuration of the piston or relative position of this piston and of this container, it closes the container in such a way as to isolate the product from the environment outside this container and, in a second configuration of the piston or relative position of this piston and of this container, it allows the product to pass out of the container". Barker et al. fails to disclose or suggest such an arrangement. In particular, the plug 190 in Barker et al. does not have different configurations for permitting injectable product to flow thereby, rather, the plug 190 is pierced by a needle to permit product flow. The piston of claim 1 has two different configurations, one which permits flow, one which does not. Barker et al. requires a needle piercing the plug 190 to obtain fluid flow. Further, Barker et al. specifically requires a fluid-tight seal to be defined about the plug 190, and, as such, there is no basis to modify Barker et al. to avoid such.

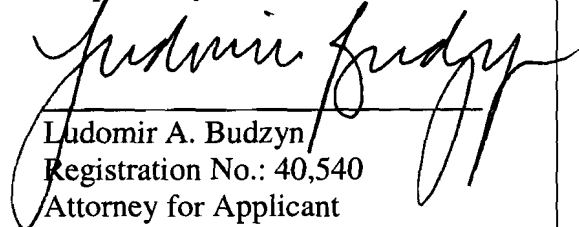
As further bases of patentability, claim 2 specifically states that "the piston is so shaped that, in said second configuration or position, it allows the product to pass between itself and the

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container” and claim 3 states that “the piston comprises at least one peripheral zone that is able, in said first configuration of the piston, to press tightly against the wall of the container, and, in said second configuration of the piston, to withdraw under the pressure of the injectable product to allow the latter to pass it.” These features are clearly not present in Barker et al. As indicated above, Barker et al. provides a fluid-tight seal about the plug 190. There is no provision to have a product pass between it and the container as set forth in claim 2. Moreover, the plug 190 does not have a peripheral zone which withdraws under pressure as set forth in claim 3. It is respectfully submitted that claims 1-8 are patentable over Barker et al.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant’s attorney at the number listed below.

Respectfully submitted,

  
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